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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/599,446

02/08/2007

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EXAMINER

ARIANI, KADE

ART UNIT

PAPER NUMBER

1651

MAIL DATE

DELIVERY MODE

09/10/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/599,446	MORIYAMA ET AL.	
	Examiner	Art Unit	
	Kade Ariani	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 1-18 are pending in this application and were examined on their merits.

Double Patenting Rejections

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-18 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-18 of US application No. 10/599,447. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are essentially reciting the same invention.

Claims 1-18 of US application No. 10/599,447 recite an agent comprising whey as an active component, acid whey, acid whey comprises fermented milk whey obtained by fermentation of milk with strain *Lactobacillus helveticus* CM4, and a functional food comprising the agent.

It would have been obvious to one skilled in the art at the time the invention was made to use the agent disclosed by US application No. 10/599,447 to provide the agent of the claimed invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

According to Stedman's Medical dictionary 27th edition, whey is the watery part of milk remaining after the separation of the casein (cheese production), thus whey and casein are two different components. Therefore, the recitation "casein whey" in claims 7 and 14 is indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 7-9, and 14-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Hageman et al. (US Patent No. 6,900,180, filing date Jan 20, 2000).

Claims 1, 2, 7-9, and 14-16 are drawn to an agent for phase-adjusting or enhancing an amplitude of an endogenous melatonin secretion rhythm comprising whey as an active component, acid whey, functional food, and improving circadian rhythm and sleep disorder.

Hageman et al. discloses an agent for phase-adjusting or enhancing an amplitude of an endogenous melatonin secretion rhythm comprising whey as an active component, acid whey, functional food, and improving circadian rhythm and sleep disorder (see Abstract, column 7, lines 46-50, column 9, lines 42-46, and column 5, lines 64-66).

Hageman et al. therefore clearly anticipates the claimed invention.

Claim Rejections - 35 USC § 102/103

Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Yamamoto et al. (US Patent 6,534,304, March 18 2003) and Heine et al. (Amino acids, 1995, Vol. 9, p. 191-205).

Claims 1-18 are drawn to an agent (for phase-adjusting or enhancing an amplitude of an endogenous melatonin secretion rhythm) comprising whey as an active component, acid whey comprises fermented milk whey obtained by fermentation of milk with lactic acid bacteria, genus *Lactobacillus*, strain *Lactobacillus helveticus* CM4, acid whey is casein whey containing an aqueous fraction, and functional food.

Yamamoto et al. discloses an agent to an agent comprising whey as an active component, acid whey comprises fermented milk whey obtained by fermentation of milk with lactic acid bacteria, genus *Lactobacillus*, strain *Lactobacillus helveticus* CM4, acid whey is casein whey containing an aqueous fraction, and functional food (see Abstract, column 1, column 7, 43-50, column 8, Example 1, lines 16-12).

Heine et al. discloses a whey protein fraction containing tryptophan, and further discloses tryptophan serves as precursor for the epiphyseal hormone melatonin, also tryptophan and its metabolites regulate neurobehavioral effects such as a sleeping-waking-rhythm and pain perception (see Abstract, p. 195, 5th paragraph).

It is noted that Yamamoto et al. does not state an agent for phase-adjusting or enhancing an amplitude of an endogenous melatonin secretion rhythm. However, claims are directed to an agent comprising fermented milk whey obtained by fermentation of milk with *Lactobacillus helveticus* CM4, the claimed whey (active component) appear to be the same or similar to that of the prior art, therefore it must necessarily have the claimed phase-adjusting or enhancing properties.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kade Ariani whose telephone number is (571) 272-6083. The examiner can normally be reached on 9:00 am to 5:30 pm EST Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

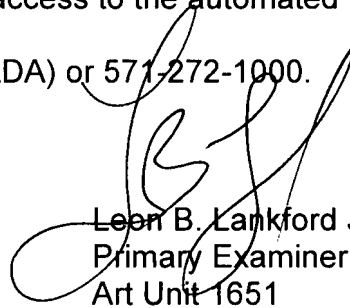
you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information

system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kade Ariani
Examiner
Art Unit 1651



Leon B. Lankford Jr.
Primary Examiner
Art Unit 1651